

01/31/02

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EL 669 271 052 US

Date of Deposit January 31, 2002.

02-0502

JC10 Rec'd PCT/PTO 31 JAN 2002

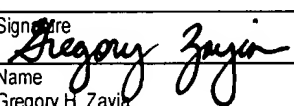
PCT

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|--|---|--|--|
| FORM PTO-1390<br>(REV. 5-93)   |   | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE | CASE NO. 9793/73   |
| TRANSMITTAL LETTER TO THE UNITED STATES<br>DESIGNATED/ELECTED OFFICE (DO/EO/US)<br>CONCERNING A FILING UNDER 35 U.S.C. 371   |   |  | U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5)<br><br>09/890,442 |
| INTERNATIONAL APPLICATION NO.<br>PCT/EP00/00602  | INTERNATIONAL FILING DATE<br>January 27, 2000 | PRIORITY DATE CLAIMED<br>January 29, 1999                  |  |
| TITLE OF INVENTION<br>ASSAY FOR THE DETECTION OF N-TERMINAL PROBNP   |   |  |  |
| APPLICANT(S) FOR DO/EO/US<br>Johann Karl, Helmut Lill, Peter Stahl, Kerstin Krueger, Anneliese Borgya, and Andreas Gallusser   |   |  |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:  |   |  |  |
| <p>1. <input type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371</p> <p>2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371</p> <p>3. <input type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).</p> <p>4. <input type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.</p> <p>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p>    a. <input type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau).</p> <p>    b. <input type="checkbox"/> has been transmitted by the International Bureau.</p> <p>    c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>    a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau).</p> <p>    b. <input type="checkbox"/> have been transmitted by the International Bureau.</p> <p>    c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p>    d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)) and/or amendments under Article 34.</p> |   |  |  |
| Items 11. to 16. Below concern other document(s) or information included:  |   |  |  |
| <p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input checked="" type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A FIRST preliminary amendment.</p> <p>    <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.</p> <p>14. <input type="checkbox"/> A substitute specification.</p> <p>15. <input checked="" type="checkbox"/> A change of power of attorney and/or address letter.</p> <p>16. <input checked="" type="checkbox"/> Other items or information: Form PCT/DO/EO/905; Form PCT/DO/EO/920; Response to Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US) (in duplicate); Response to Notification to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures; Petition and Fee for Three (3) Month Extension of Time (in duplicate); Check for \$920; Duplicate 3.5" Diskette containing Sequence Listing; Substitute Paper Copy of Sequence Listing (2 pages); and Return Postcard.</p>   |   |  |  |



00757

PATENT TRADEMARK OFFICE

|   |              |   |            |   |  |              |  |
|---|--------------|---|------------|---|--|--------------|--|
| U.S. APPLICATION NO. (if known, see 37 C.F.R. 1.50)<br>09/890,442   |              | INTERNATIONAL APPLICATION NO.<br>PCT/EP00/00602 |            | CASE NO. 9793/73  |  |              |  |
| 17. <input type="checkbox"/> The following fees are submitted:<br><b>Basic National Fee (37 CFR 1.492(a)(1)-(5)):</b><br>Search Report has been prepared by the EPO or JPO..... \$890.00<br><br>International preliminary examination fee paid to USPTO<br>(37 CFR 1.492(a)(1))..... \$710.00<br><br>No international preliminary examination fee paid to USPTO<br>(37 CFR 1.482) but international search fee paid to USPTO<br>(37 CFR 1.492(a)(2))..... \$740.00<br><br>Neither international preliminary examination fee (37<br>CFR 1.482) nor international search fee (37 CFR<br>1.492(a)(3)) paid to USPTO..... \$1,040.00<br><br>International preliminary examination fee paid to<br>USPTO (37 CFR 1.482) and all claims satisfied<br>provisions of PCT Article 33(1)-(4)..... \$100.00<br><br><div style="text-align: center; font-weight: bold; margin-top: 10px;">ENTER APPROPRIATE BASIC FEE AMOUNT</div> |              |   |            | CALCULATIONS  |  | PTO USE ONLY |  |
|   |              |   |            |   |  |              |  |
|   |              |   |            |   |  |              |  |
|   |              |   |            |   |  |              |  |
|   |              |   |            |   |  |              |  |
| Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed<br>priority date (37 CFR 1.492(e)).   |              |   |            | \$130   |  |              |  |
| Claims  | Number Filed | Number Extra                                    | Rate       |   |  |              |  |
| Total Claims  | - 20 =       |   | x \$ 18.00 |   |  |              |  |
| Independent Claims  | - 3 =        |   | x \$ 84.00 |   |  |              |  |
| Multiple dependent claim(s) if Applicable) 0  |              |   |            | + \$280.00  |  |              |  |
| TOTAL OF ABOVE CALCULATIONS =   |              |   |            | \$  |  |              |  |
| Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37<br>CFR 1.9, 1.27, 1.28)  |              |   |            |   |  |              |  |
| SUBTOTAL =  |              |   |            | \$130   |  |              |  |
| Surcharge of \$130.00 for furnishing the English translation later than the <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest<br>claimed priority date (37 CFR 1.492(f)).  |              |   |            | \$  |  |              |  |
| TOTAL NATIONAL FEE =  |              |   |            | \$  |  |              |  |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an<br>appropriate cover sheet (37 CFR 3.28, 3.31), \$40.00 per property +   |              |   |            | 40.00   |  |              |  |
| TOTAL FEES ENCLOSED =   |              |   |            | \$170   |  |              |  |
|   |              |   |            | Amount to be<br>refunded  |  | \$           |  |
|   |              |   |            | charged   |  | \$           |  |
| a. <input checked="" type="checkbox"/> Checks in the amounts of \$130 and \$40 to cover the above fees are enclosed.<br>b. <input type="checkbox"/> Please charge my Deposit Account No. 23-1925 in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed.<br>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No.<br>23-1925. A duplicate copy of this sheet is enclosed.   |              |   |            |   |  |              |  |
| NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to<br>restore the application to pending status.  |              |   |            |   |  |              |  |
| Send All Correspondence to:<br>Brinks Hofer Gilson & Lione<br>P.O. Box 10395<br>Chicago, IL 60610<br><br>02/08/2002 MHGUYEN 00000088 09890442<br><br>01 FC:154 130.00 OP  |              |   |            | Signature<br><br>Name<br>Gregory H. Zayin<br>Registration Number 48,059 |  |              |  |

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Date of Deposit: January 31, 2002

Case No. 9793/73

**IN THE UNITED STATES PATENT & TRADEMARK OFFICE**

|                       |  |   |                                |
|-----------------------|--|---|--------------------------------|
| In re Application of: | Johann Karl et al.                           | ) |                                |
|                       |  | ) |                                |
|                       |  | ) |                                |
|                       |  | ) | Examiner: To Be Assigned       |
| Serial Number:        | 09/890,442                                   | ) |                                |
|                       |  | ) | Group Art Unit: To Be Assigned |
| Filing Date:          | July 26, 2001                                | ) |                                |
|                       |  | ) |                                |
| Title:                | Assay for the Detection of N-Terminal proBNP | ) |                                |
|                       |  | ) |                                |

**RESPONSE TO NOTIFICATION TO COMPLY WITH REQUIREMENTS  
FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE  
AND/OR AMINO ACID SEQUENCE DISCLOSURES**

Commissioner for Patents  
Washington D.C. 20231

Dear Sir:

In response to the Notification to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures (copy attached herewith), applicants state the following:


In a telephone conversation with the undersigned agent on November 19, 2001, Ms. India Evans of the United States Patent and Trademark Office stated that the original 3.5" diskette containing the sequence listing for the above-identified patent application was received together with the other application materials filed on July 26, 2001. Nonetheless, Applicants submit herewith a duplicate 3.5" diskette

containing the sequence listing. As required under 37 C.F.R. § 1.821, Applicants note that the sequence listing information recorded in computer readable form is identical to the written sequence listing.

In addition, Applicants note that a paper copy of the sequence listing was already submitted as part of the English translation of the International Application filed on July 26, 2001. A substitute paper copy of the sequence listing (pages 29 and 30 of the English translation filed on July 26, 2001) are attached herewith.

It is respectfully submitted that the Applicants are in full compliance with the requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Respectfully submitted,

  
\_\_\_\_\_  
Gregory H. Zayia  
Registration No. 48,059  
Agent for Applicants

BRINKS HOFER GILSON & LIONE  
P.O. BOX 10395  
CHICAGO, IL 60610  
(312) 321-4200

Rec'd PCT/PTO 31 JAN 2002

"Express Mail" mailing label number

EL 669 271 052 US

Date of Deposit:

January 31, 2002

Case No. 9793/73

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Johann Karl et al.

Serial No.: 09/890,442

Attention: Manager,  
Application Branch

Filed: July 26, 2001

For: Assay for the Detection of  
N-Terminal proBNP

**RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS UNDER 35  
U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE  
(DO/EO/US)**

Commissioner for Patents  
Washington, D.C. 20231

Attn.: Box Missing Parts

Dear Sir:

In response to the Notification of Missing Requirements under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US) mailed September 20, 2001, a copy of which is attached, enclosed herewith for filing are the following documents:

☒ Fully executed Declaration for Patent Application and Power of Attorney for the above-referenced patent application.

☒ Applicant is:

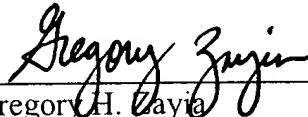
☐ a small entity, verified statement is:

☐ attached

- ☐ already filed
- ☒ other than small entity
- ☒ Checks totaling \$1050 for:
- ☒ Extension of Time Fee of \$920.
- ☒ Surcharge of \$130.
- ☐ Additional Claim Fees of \$\_\_\_\_.
- ☒ Petition for Extension of Time (37 C.F.R. § 1.136(a)) to file missing parts (in duplicate).
- ☒ Other: Form PCT/DO/EO/920; Response to Notification to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures; Duplicate 3.5" Diskette containing Sequence Listing; Substitute Paper Copy of Sequence Listing (2 pages); Assignment Transmittal; Assignment; Check for \$40; Return Postcard.
- ☒ The Commissioner is hereby authorized to charge any deficiencies in fees or credit overpayment to Deposit Account No. 23-1925. A duplicate copy of this paper is enclosed.

Respectfully submitted,

Dated: January 31, 2002

  
\_\_\_\_\_  
Gregory H. Layia  
Registration No. 48,059  
Agent for Applicants

BRINKS HOFER GILSON & LIONE  
P.O. BOX 10395  
CHICAGO, IL 60610  
(312) 321-4200



## UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents, Box PCT  
United States Patent and Trademark Office  
Washington, D.C. 20231  
www.uspto.gov

|                               |                       |                  |
|-------------------------------|-----------------------|------------------|
| U.S. APPLICATION NO.          | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 09/890442                     | KARL J                | 9793/73          |
| INTERNATIONAL APPLICATION NO. |                       |                  |

JEFFREY M DUNCAN  
BRINKS HOFER GLISON & LIONE  
PO BOX10395  
CHICAGO, IL 60610

PCT/EP00/00602

|                  |               |
|------------------|---------------|
| I.A. FILING DATE | PRIORITY DATE |
| 27 JAN 00        | 29 JAN 99     |

DATE MAILED:

20 SEP 2001

**NOTIFICATION TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS  
CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE  
DISCLOSURES**

Applicant has submitted papers under 35 U.S.C. 371 to enter the national stage in the United States of America. The items indicated below, however, are missing. The period within which to correct the deficiency noted below and avoid abandonment is set forth in the accompanying Notification.

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reason(s):

- ☒ The application fails to comply with the requirements of 37 CFR 1.821-1.825.
- ☐ This application does not contain, a "Sequence Listing" as a separate part of the disclosure on paper copy or compact disc, as required by 37 CFR 1.821(c).
- ☒ A copy of the "Sequence Listing" in computer readable format has not been submitted as required by 37 CFR 1.821(e).
- ☐ A copy of the "Sequence Listing" in computer readable form has been submitted. The content of the computer readable form, however, does not comply with the requirements of 37 CFR 1.822 and/or 1.832, as indicated on the attached marked-up copy of the "Raw Sequence Listing."
- ☐ The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).
- ☐ The paper copy or compact disc of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).
- ☐ Other: \_\_\_\_\_

**APPLICANT MUST PROVIDE:**

- ☐ An initial or substitute computer readable form (CRF) of the "Sequence Listing."
- ☒ An initial or substitute paper copy or compact disc of the "Sequence Listing," as well as an amendment directing its entry into the specification.
- ☒ A statement that the contents of the paper or compact disc and the computer readable form are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d).

**FOR QUESTIONS REGARDING COMPLIANCE WITH THESE REQUIREMENTS, PLEASE  
CALL:**

(703) 308-4216, for Rules interpretation,  
(703) 308-4212, for CRF submission help,  
(703) 287-0200, for PatentIn software help.

India Evans

Telephone: 703-305-2936



## UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents, Box PCT  
United States Patent and Trademark Office  
Washington, D.C. 20231  
www.uspto.gov

|                               |                       |                  |
|-------------------------------|-----------------------|------------------|
| U.S. APPLICATION NO.          | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 09/890442                     | KARL J                | 9793/73          |
| INTERNATIONAL APPLICATION NO. |                       |                  |

JEFFREY M DUNCAN  
BRINKS HOFER GLISON & LIONE  
PO BOX10395  
CHICAGO, IL 60610

PCT/EP00/00602

|                  |               |
|------------------|---------------|
| I.A. FILING DATE | PRIORITY DATE |
| 27 JAN 00        | 29 JAN 99     |

DATE MAILED:

20 SEP 2001

**NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)**

1. The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as ☐ a Designated Office (37 CFR 1.494) ☒ an Elected Office (37 CFR 1.495):

- |  |  |
|--|--|
| <input checked="" type="checkbox"/> U.S. Basic National Fee.   | <input type="checkbox"/> Indication of Small Entity Status.                                    |
| <input checked="" type="checkbox"/> Copy of the international application.   | <input checked="" type="checkbox"/> Translation of the international application into English. |
| <input type="checkbox"/> Oath or Declaration of inventors(s).  | <input type="checkbox"/> Translation of Article 19 amendments into English.                    |
| <input type="checkbox"/> Copy of Article 19 amendments.  | <input type="checkbox"/> Other:  |
| <input checked="" type="checkbox"/> Priority Document.   |  |
| <input type="checkbox"/> The International Preliminary Examination Report in English and its Annexes, if any.                |  |
| <input checked="" type="checkbox"/> Translation of Annexes to the International Preliminary Examination Report into English. |  |

2. ☐ Applicant has requested early processing under 35 U.S.C. 371(f) but has not filed the following indicated items and/or the indicated items in paragraph 3 below. The Basic National Fee and the copy of the international application must be filed prior to 20 or 30 months from the priority date to avoid abandonment.

- |   |   |
|---|---|
| <input type="checkbox"/> U.S. Basic National Fee. | <input type="checkbox"/> Copy of the international application. |
|---|---|

3. The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- ☐ a. Translation of the application into English. A processing fee will be required if submitted later than the appropriate 20 or 30 months from the priority date.
- ☐ The current translation is defective for the reasons indicated on the attached Notice of Defective Translation.
- ☐ b. Processing fee for providing the translation of the application and/or the Annexes later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(f)).
- ☒ c. Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), properly identifying the application (preferably by the International application number and international filing date). A surcharge will be required if submitted later than the appropriate 20 or 30 months from the priority date.
- ☐ The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) for the reasons indicated on the attached PCT/DO/EO/917.
- ☒ d. Surcharge for providing the oath or declaration later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(e)).

4. Additional claim fees of \$\_\_\_\_\_ as a ☐ large entity ☐ small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due (37 CFR 1.492(g)). See attached PTO-875.

5. ☒ Applicant has not submitted the required sequence listing pursuant to 37 CFR 1.821-1.825. See attached PCT/DO/EO/920.

**ALL OF THE ITEMS SET FORTH IN 3(a)-3(d), 4 AND 5 ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 22 OR 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

6. If box 3a or 3c is checked, a translation of the Annexes **MUST** be submitted no later than the time period set above or the Annexes will be cancelled. A processing fee will be required if submitted later than 20 or 30 months from the priority date.
7. ☐ The Article 19 amendments are cancelled since a translation was not provided by the appropriate 20 (37 CFR 1.494(d)) or 30 (37 CFR 1.495(d)) months from the priority date.

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

***A copy of this notice MUST be returned with this response.***

Enclosed: ☐ PCT/DO/EO/917 ☐ Notice of Defective Translation  
☐ PTO-875 ☒ PCT/DO/EO/920

India Evans

FORM PCT/DO/EO/905 (March 2001)

Telephone: 703-305-2936